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A REVIEW ON ANALYTICAL METHOD FOR DETERMINATION OF NETUPITANT AND PALONOSETRON IN PHARMACEUTICAL FORMULATION

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ABSTRACT

Nausea and vomiting are the important adverse reaction/effects of Chemotherapy that effect the treatment as well as the health related quality of life. A FIXED combination of Netupitant and Palonosetron is use in the prevention of acute and delayed Chemotherapy-induced nausea and vomiting (CINV). This drug's, clinical and pharmaceutical analysis requires effective analytical procedures and stability studies. Netupitant is a highly selective neurokinin-1 receptor antagonist and Palonosetron is a serotonin 5-HT_3 receptor antagonist with a distinct pharmacological profile. It also exhibits prolonged efficacy to provide significantly better protection from nausea and vomiting (CINV). This review paper presents an overview of analytical and chromatographic methods reported for the analysis of Netupitant and Palonosetron in pharmaceutical formulations.

KEYWORDS: Netupitant, Palonosetron, CINV, Analytical methods.

INTRODUCTION

Netupitant, chemically known as 2-[3,5-bis(trifluoromethyl)phenyl]-N,2-dimethyl-N-[4-(2-methylphenyl)-6-(4-methylpiperazn-1-yl)pyridin-3-yl]propanamide, having chemical formula $C_{30}H_{32}F_6N_4O$ and molecular weight 578.61 g/mol. It is a selective neurokinin 1 (NK1) receptor antagonist with potential antiemetic activity brought through with the activation of NK11 receptor and substance P. It is an antiemetic agent used in combination with Palonosetron to prevent acute and delayed vomiting and nausea caused by chemotherapy.

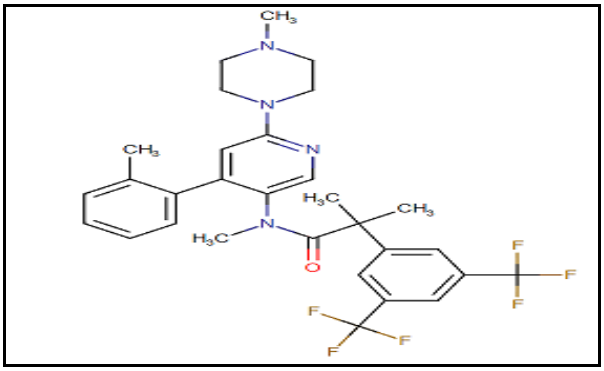

Figure 1: Structure of netupitant.

Palonosetron, chemically known as (3aS)-2-[(3S)-1-azabicyclo[2.2.2]octan-3-yl]-3a,4,5,6-tetrahydro-3H-benzo[de]isoquinolin-1-one hydrochloride, having chemical formula $C_{19}H_{25}ClN_2O$ and molecular weight 332.87 g/mol. It is a selective and specific serotonin 5-HT3 antagonist with antinauseant and antiemetic activity brought through the inhibition of 5-HT3 receptor present both in central (medullary chemoreceptor zone) and peripherally (GI tract) leads to prevention of nausea and vomiting.

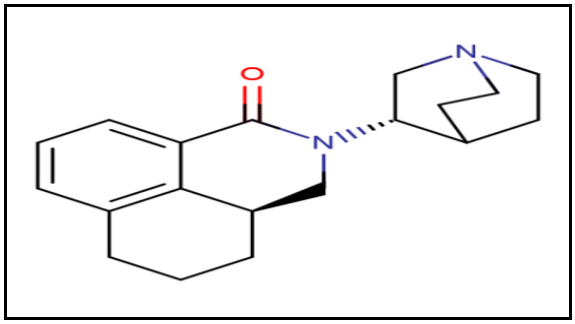

Figure 2: Structure of palonosetron.

Table: Summary of Analytical methods of Netupitant and Palonosetron.

Title	Method	Mobile phase	Stationary phase	Wavelength	Ref
A novel validated RP-HPLC-DAD method for simultaneous estimation of Netupitant and Palonosetron in bulk and pharmaceutical dosage form with forced degradation studies	RP-HPLC-DAD	0.01M Ammonium acetate buffer and Acetonitrile (65:35, v/v)	Kromasil C18 column (250mm×4.6mm, 5mm particle size)	265nm	[1]

Stability indicating method development and validation for the simultaneous estimation of Palonosetron and Netupitant by RP-HPLC in bulk form.	HPLC	Methanol: water (45:55 v/v)	C-18 Inertsil-ODS 3V column (250 X 4.6 mm, 5 µm)	236nm	[2]
A Validated stability indicating RP-HPLC method for simultaneous determination of Netupitant and Palonosetron in pharmaceutical formulation.[3]	RP-HPLC	Phosphate buffer: acetonitrile (40:60% v/v)	Thermo BDS C 18 (150 mm x 4.6 mm 5µ)	210nm	[3]
Development and validation of stability indication RP-HPLC method for the estimation of Netupitant and Palonosetron in combined tablet dosage form.	RP-HPLC	0.1% orthophosphoric acid: Methanol (55:45 v/v)	YMC Pack pro (150 mm x 4.6 mm, 5 µm particle size) C18 column	262nm	[4]
Simultaneous quantitative estimation of Netupitant and Palonosetron HCl by HPTLC method development and validation.	HPTLC	Dichloromethane: Ethyl acetate: Triethyleamine: Methonol (5:3:1.5:0.5)	Aluminium plates precoated with silica gel	241nm	[5]
Development and validation of a rapid LC-MS/MS method in human plasma and its application to a pharmacokinetic study.	LC-MS/MS	Acetonitrile and 10m ammonium acetate buffer (pH 9.0) (89:11, v/v)	Phenomenex C18 column (50mm x 2.0mm, 3 µm)	-	[6]
Development and validation of RP-HPLC method for	RP-HPLC	Acetonitrile:Phosphate buffer (80:20 % v/v)	Symmetry C18 (4.6 x 150mm, 5	274nm	[7]

simultaneous estimation of Netupitant and Palonosetron in pharmaceutical dosage form.			µm)		
Method development and validation for simultaneous quantification of Netupitant and Palonosetron in bulk and pharmaceutical dosage form and their forced degradation study by RP-HPLC.	RP-HPLC	0.1% orthophosphoric acid:acetonitrile (60:40 v/v)	Luna C18 (250 mm x 4.6mm, 5 µm)	222nm	[8]
Development and validation of stability indicating HPLC method for simultaneous estimation of Fosnetupitant and Palonosetron in pharmaceutical dosage form.[9]	RP-HPLC	Methanol:Acetonitrile:1% sodium perchlorate (75;20:05 v/v/v)	Synchronies C-18 (250mm x 4.6mm, 5 µm)	263 nm	[9]
Development and validation of stability indicating UPLC method for the estimation of Palonosetron in bulk and it pharmaceutical dosage form.	UPLC	Buffer:acetonitrile (65:35)	BEH C18100 mm x 2.1 mm, 1.8 µm)	240nm	[10]
Analytical method development and validation of Netupitant tablets by using RP-HPLC Techniques.	RP-HPLC	potassium dihydrogen phosphate(pH2.5): acetonitrile (35:65 v/v) HPLC Symmetry C18 (4.6x 150mm, 5µm)	HPLC Symmetry C18 (4.6x 150mm, 5µm)	235nm	[11]
Estimation of Palonosetron	UV	_	_	265 nm	[12]

hydrochloride (a 5-HT_3 antagonist) on pharmaceutical dosage form by U.V spectrophotometric method.					
A Novel Validated RP-HPLC Method For The Simultaneous Estimation Of Netupitant And Palonosetron In Bulk And Pharmaceutical Dosage Form	RP-HPLC	0.01M Triethylamine buffer and acetonitrile (60:40, v/v)	Luna Phenyl Hexyl (250mmx 4.6mm, 5mm particle size)	222nm	[13]
A Photo Stability Indicating HPLC Technique For Validation Of Netupitant And Palonosetron In Bulk And Formulations	RP-HPLC	Orthophosphoric and acetate buffer and methanol (70:30)	YMC (4.6×150mm 5µ)	210nm	[14]
Development and validation of HPLC method for simultaneous estimation of Netupitant and Palonosetron in pharmaceutical dosage form	HPLC	potassium dihydrogen phosphate: Methanol (70:30 v/v)	YMC Pack pro (150 mm x 4.6 mm, 5 µm particle size) C18 column	210nm	[15]

CONCLUSION

Various analytical methods have been reported for the determination of Netupitant and Palonosetron in pharmaceutical formulation. The most commonly used analytical technique is HPLC. A few chromatographic methods are listed in the table above High Sensitivity, good reproducibility, specificity, high resolution and better separation capacity favours HPLC to be used for the Qualitative and Quantitative analysis of Netupitant and Palonosetron.

A simple, rapid and reproducible stability indicating RP-HPLC method was determined for the analysis of Netupitant and Palonosetron in bulk and pharmaceutical dosage forms. The method was validated according to ICH guidelines.

The above mentioned information is beneficial for the future research involving in the quality control of Netupitant and Palonosetron in bulk and pharmaceutical formulation.

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